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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/587,732

05/17/2007

Andrew Ian Cooper

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EXAMINER

NEGRELLI, KARA B

ART UNIT

PAPER NUMBER

1796

MAIL DATE

DELIVERY MODE

03/18/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/587,732	COOPER ET AL.	
	Examiner	Art Unit	
	KARA NEGRELLI	1796	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 August 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08/24/2006</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the “right to exclude” granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-22 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/587,734. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the referenced claims are directed to the same subject matter which is: a porous body comprising water-soluble polymer, surfactant, and a hydrophobic material and a method of making a porous body containing water-soluble polymer and surfactant. The instant claims and the claims of the reference are nearly identical with the exception that the instant application requires less than 10% by weight of a water-soluble polymeric

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material other than a surfactant, 5 to 95% by weight of a surfactant, and a hydrophobic material to be dispersed when the polymeric material dissolves, while the copending application requires 10% - 95% by weight of a water-soluble polymeric material other than a surfactant, 5 to 95% by weight of a surfactant, and does not teach a hydrophobic material in claim 1. Although the amount of polymeric material is 10% to 95% in the reference and less than 10% in the instant application, it is the examiner's position that the values are close enough that one of ordinary skill in the art would have expected the same properties. Case law holds that a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). Furthermore, although the hydrophobic material of instant claim 1 is not recited in claim 1 of the reference application, the hydrophobic material is recited in claims 8 and 10 of the reference application.

This is a provisional obviousness-type double patenting rejection.

Claims 1-3, 5, 8-14, 16, and 18-20 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5-10, and 12-18 of copending Application No. 10/587,722. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the referenced claims are directed to the same subject matter which is: a porous body comprising water-soluble polymer, surfactant, and a hydrophobic material and a method of making a porous body containing water-soluble polymer and

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surfactant. The instant claims and the claims of the reference are nearly identical with the exception that the instant application requires less than 10% by weight of a water-soluble polymeric material other than a surfactant, 5 to 95% by weight of a surfactant, and a hydrophobic material to be dispersed when the polymeric material dissolves, while the copending application requires 10% - 95% by weight of a water-soluble polymeric material other than a surfactant, 5 to 95% by weight of a surfactant, and does not teach a hydrophobic material in claim 1. Although the amount of polymeric material is 10% to 95% in the reference and less than 10% in the instant application, it is the examiner's position that the values are close enough that one of ordinary skill in the art would have expected the same properties. Case law holds that a prima facie case of obviousness exists where the claimed ranges and prior art ranges do not overlap but are close enough that one skilled in the art would have expected them to have the same properties. *Titanium Metals Corp. of America v. Banner*, 778 F.2d 775, 227 USPQ 773 (Fed. Cir. 1985). Furthermore, although the hydrophobic material of instant claim 1 is not recited in claim 1 of the reference application, the hydrophobic material is recited in claims 8 and 10 of the reference application.

This is a provisional obviousness-type double patenting rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3-4, 11, 13, and 16 are rejected under 35 U.S.C. 102 (b) as being anticipated by Fujimoto et al. (Patent Abstracts of Japan, Publication no. 01011141).

As to claims 1-3, 11, 13, 16, and 20-22 Fujimoto (Abstract, 62166603) teaches a porous article by combining an aqueous solution, a uniform aqueous suspension or the mixture of a hydrophilic polymer (cellulose or polyvinyl alcohol) having a concentration of 0.05 to 50%, preferably 0.1 to 10% with 0.5 to 50% of surfactant having an HLB value of 2 to 20, and freeze drying the mixture to attain a product of thickness 5-100 mm.

Fujimoto et al. fail to explicitly teach that the polymeric compositions have an intrusion volume as measure by mercury porosimetry of at least about 3 mL/g. However, since the same composition that is disclosed in claim 1 is taught in Fujimoto et al., one of ordinary skill in the art would expect that the composition of Fujimoto et al. would have the same properties as the composition disclosed in claim 1, and would therefore have the specified intrusion volume.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (US 5,025,004) and further in view of Kitagawa (US 6,048,908).

As to claims 1 and 2, Wu et al. teach a process for preparing solid, powdered, polymeric compositions (column 3, lines 6-8), said powdered compositions of which are readily dispersible in water (column 3, lines 18-22) comprising at least one polymeric, water soluble or water dispersible, nonionic emulsifier (column 3, lines 51-53) in an amount of from 0.5 to 70% (column 4, lines 17-18) and additionally comprising an additive in an amount from 10 to 25% weight which can include surfactants such as Tween 80 (column 8, lines 51-60). The powders taught by Wu et al. have a particle size in the range of from 10 μm to 30 μm (meaning the particles are not spheres with a diameter of from 0.2 to 0.5 mm) (column 8, lines 37-39). Wu et al. fail to explicitly teach that the polymeric compositions have an intrusion volume as measure by mercury porosimetry of at least about 3 mL/g. However, since the same composition that is disclosed in claim 1 is taught in Wu et al., one of ordinary skill in the art would expect that the composition of Wu et al. would have the same properties as the composition disclosed in claim 1, and would therefore have the specified intrusion volume.

Wu et al. do not specify that the powdered polymeric materials are porous. However, Kitagawa teaches porous hydrophilic microbeads, produced using a formulation which comprises from 0.5 to 50% by weight monomer (column 7, lines 53-56) and 1 to 30% weight of surfactant (column 9, lines 4-8), said microbeads of which are used for drug carriers (column 15, lines 3-7). One of ordinary skill in the art would

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expect that if the powdered polymeric compositions of Wu et al. were porous, it would aid the medicaments for which it is used (column 3, lines 5-10) in distribution throughout the body (Kitagawa, (US 6,048,908), column 15, lines 4-5).

As to claims 3-4, Wu et al. teach the process for preparing the composition as applied to claim 1, wherein the polymeric material can comprise cellulose acetate (column 6, lines 11).

As to claims 5 and 7 Wu et al. teach the process for preparing a composition as applied to claim 1 in which the surfactant is nonionic Tween 80, polyethylene glycol sorbitan monooleate (column 8, line 60).

As to claim 6, Wu et al. do not specify that the surfactant used in the invention is solid at ambient temperature. However, Kitagawa teaches the use of distearate as a surfactant which is solid at room temperature (column 8, lines 52-54).

As to claims 8-9 and 22 Wu et al. teach the process for preparing the composition as applied to claim 1, further comprising at least one water insoluble polymer (column 8, lines 25-26) and a water soluble polymers (column 8, lines 56-59). Wu et al. further teach dispersing the powdered, polymeric composition into an aqueous solution (column 8, lines 45-46).

As to claim 10, Wu et al. teach the process for preparing the composition as applied to claim 1, and further teach that said composition can be used to prepare a cosmetic composition, said cosmetic composition of which contains at least one active ingredient such as a UV absorber (column 9, lines 45-53).

Claims 11-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wu et al. (US 5,025,004) and further in view of Kitagawa (US 6,048,908) and Monforte et al. (US 3,551,533)

As to claim 11-12, Wu et al. teach preparing solid, powdered, polymeric compositions (column 3, lines 6-8), said powdered compositions of which are readily dispersible in water (column 3, lines 18-22) comprising at least one polymeric, water soluble or water dispersible, nonionic emulsifier (column 3, lines 51-53) in an amount of from 0.5 to 70% (column 4, lines 17-18) and additionally comprising an additive in an amount from 10 to 25% weight which can include surfactants such as Tween 80 (column 8, lines 51-60). Wu et al. further teach that the composition contains at least one water-in-oil emulsifier (column 3, lines 50-68).

Wu et al. further disclose that the composition comprises an organic solvent (liquid medium) (column 3, lines 44-48). Wu et al. also teach passing the polymer solution-in-water emulsion through a particle size reduction means such that the polymer is in the form of droplets having an average size in the range of about 0.1 to 0.8 μm , followed by removing the organic solvent to form aqueous dispersion, and drying the dispersion to form the water dispersible powder (column 4, lines 45-62). Wu et al. teach drying the particles by freeze drying (column 8, lines 17-20).

Neither Wu et al. nor Kitagawa teach the steps of freeze drying the porous materials. One of ordinary skill in the art would recognize that freeze drying employs a fluid freezing medium used to rapidly freeze a composition and further employs drying by sublimation. For example, Monforte et al. teaches breaking up a solute material into

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fine droplets, rapidly freezing the droplets to prevent coalescence (freeze-drying) and removal of the solvent by sublimation (column 1, lines 46-54). The dried droplets of Monforte et al. are porous (column 1, line 57).

As to claims 13, Wu et al. teach the process for preparing the composition as applied to claim 1, wherein the polymeric material can comprise cellulose acetate (column 6, lines 11).

As to claims 14 and 16-17, Wu et al. teach the process for preparing a composition as applied to claim 1 in which the surfactant is nonionic Tween 80, polyethylene glycol sorbitan monooleate (column 8, line 60).

As to claim 15, Wu et al. do not specify that the surfactant used in the invention is solid at ambient temperature. However, Kitagawa teaches the use of distearate as a surfactant which is solid at room temperature (column 8, lines 52-54).

As to claim 18-19, Wu et al. and Kitagawa teach the polymeric compositions as applied to claim 11. Kitagawa teaches porous hydrophilic microbeads, produced using a formulation which comprises from 0.5 to 50% by weight monomer (column 7, lines 53-56) and 1 to 30% weight of surfactant (column 9, lines 4-8), said microbeads of which are used for drug carriers (column 15, lines 3-7). Kitagawa further teaches that the discontinuous oil phase can be about 10%, about 20%, about 30%, about 40%, about 50% or about 60%, and as high as 99% of the emulsion (column 11, lines 38-50).

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As to claim 20, Wu et al. and Kitagawa teach the polymeric compositions as applied to claim 11 which further comprises solvents including alicyclic hydrocarbons, ethers, and esters (column 5, lines 31-43).

As to claim 21-22, Wu et al. teach the composition as applied to claim 11 and further teach dispersing the powdered, polymeric composition into an aqueous solution (column 8, lines 45-46).

It would have been obvious for one of ordinary skill in the art to combine Wu et al. and Kitagawa because both disclose compositions comprising acrylate polymers (Kitagawa, column 7, lines 27-28; Wu et al., column 6, line 29) and surfactants (Kitagawa, column 8, lines 54; Wu et al., column 8, line 60) to make hydrophilic, water dispersible products used in pharmaceuticals (Kitagawa, column 15, lines 4-6; Wu et al., column 3, line 6-9).

Cooper et al. (WO 03/091321) and Kitagawa are not anticipatory references because both (US 6,048,908, also WO 99/00187) teach spherical beads with a diameter in the range that the instant application claims the instant water dispersible porous articles are NOT to be. Neither reference teaches freeze-drying of the porous particles.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to KARA NEGRELLI whose telephone number is

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(571)270-7338. The examiner can normally be reached on Monday through Friday 8:00 am EST to 5:00 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Randy Gulakowski can be reached on (571)272-1302. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/KARA NEGRELLI/
Examiner, Art Unit 1796

/Randy Gulakowski/

Supervisory Patent Examiner, Art Unit 1796

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